

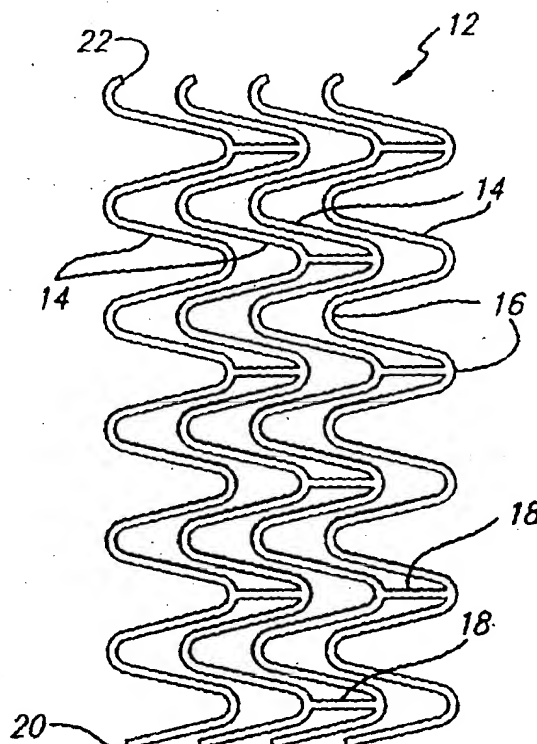
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US99/13618 (22) International Filing Date: 16 June 1999 (16.06.99) (30) Priority Data: 09/099,008 17 June 1998 (17.06.98) US (71) Applicant: ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 95054-8167 (US). (72) Inventor: COX, Daniel, L.; 191 Washington Avenue, Palo Alto, CA 94301 (US). (74) Agents: MAHER, Pamela, G. et al.; Fulwider Patton Lee & Utecht, LLP, 10th floor, 10877 Wilshire Boulevard, Los Angeles, CA 90024 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i>

(54) Title: EXPANDABLE STENT AND METHOD OF USE**(57) Abstract**

A configuration for expandable stents wherein a series of circumferentially disposed serpentine elements are spaced such that apexes defined by adjacent serpentine elements are nested within one another and only apexes extending along the same side of each serpentine element are linked. Such configurations impart enhanced coverage areas, expansion ratios and radial strength to the stent.



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EXPANDABLE STENT AND METHOD OF USE

BACKGROUND OF THE INVENTION

The present invention generally relates to intravascular stents and more particularly pertains to improvements thereto that provide for increased coverage and greater expansion ratios without a compromise in strength.

5 Stents or expandable grafts are implanted in a variety of body lumens in an effort to maintain their patency. These devices are typically intraluminally implanted by use of a catheter which is inserted at an easily accessible location and then advanced to the deployment site. The stent is initially in a radially compressed or collapsed state to enable it to be maneuvered through the lumen. Once in
10 position, the stent is deployed which, depending upon its configuration, is achieved either automatically or actively by the inflation of a balloon about which the stent is carried on the catheter.

As stents are normally employed to hold open an otherwise blocked, constricted or occluded lumen, a stent must exhibit sufficient radial or hoop strength
15 in its expanded state to effectively counter the anticipated forces. Not only is it advantageous to distribute such loads over as much of the stent as possible but it also is most beneficial to distribute the load over as much lumen wall as possible. This will help minimize injury to the vessel wall. Also by minimizing the gaps between stent struts it is possible to prevent prolapse of the plaque between the
20 struts into the lumen. As a consequence, it is desirable to maximize the coverage of the lumen wall by creating uniform, small gaps between the stent struts. It is, however, simultaneously necessary for the stent to be as small and compact as possible in its collapsed state in order to facilitate its advancement through the lumen. As large an expansion ratio as possible is therefore most desirable.

25 A number of very different approaches have been previously devised in an effort to address these various requirements. A popular approach calls for the stent to be constructed wholly of wire. The wire is bent, woven and/or coiled to

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define a generally cylindrical structure in a configuration that has the ability to undergo radial expansion. The use of wire has a number of disadvantages associated therewith including for example, a substantially constant cross-section which may cause greater or lesser than an ideal amount of material to be

5 concentrated at certain locations along the stent. Additionally, wire has limitations with respect to the shapes it can be formed into thus limiting the expansion ratio, coverage area and strength that can ultimately be attained therewith. The welding of adjoining sections of wire together has also been previously employed to increase strength albeit with a substantial increase in manufacturing costs.

10 As an alternative to wire-based structures, stents have been constructed from tube stock. By selectively removing material from such tubular starting material, a desired degree of flexibility and expandability can be imparted to the structure. Chemical etching techniques as well as laser-cutting processes are utilized to remove material from the tube. Laser etching provides for a high degree
15 of precision and accuracy with which very well defined patterns of material can be removed from the tube to conversely leave very precisely and accurately defined patterns of material in tact. The performance parameters of such stents are very much a function of the pattern in which material is removed from the tube stock. The selection of a particular pattern has a profound effect on the coverage area,
20 expansion ratio and strength of the resulting stent.

While the tube-based stents offer many advantages over the wire-based designs, it is nonetheless desirable to improve upon such designs in an effort to further increase coverage area and expansion ratios while maintaining strength.

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SUMMARY OF THE INVENTION

The present invention provides for an improved tube-based stent having an increased coverage area, expansion ratio and strength. The improvements arise with the selection of a precisely defined pattern of voids that are cut or etched into the tube stock. The pattern of material that remains to define the stent comprises a series of nested serpentine elements wherein selected apexes are interconnected to one another by bridging members. More particularly, each serpentine element extends circumferentially about the stent such that successive apexes of each element alternatively extend distally and proximally along the stent's surface. Adjacent serpentine elements are spaced about the stent wherein each element is nested in the adjacent elements such that the apexes of one element extend into the space between the apexes of the adjacent element. The serpentine elements are joined to one another along either all of their distal or all of their proximal apexes. Each of a particular element's apexes extending along its interconnected edge is alternately joined to the corresponding apexes of proximally and distally adjoining serpentine elements by bridging elements. By properly shaping the junction area between each bridging element and apex, stress risers are reduced or eliminated with a corresponding decrease in the potential for fracturing during expansion. By curving the transverse sections that extend between each of the apexes of a given element, adjacent elements become more tightly packed. Coverage exceeding 20% with expansion ratios of 3.0 are thereby achievable, and expansion ratios exceeding 6.0 are also achievable. More importantly, this dense coverage is uniformly distributed throughout the stent.

These and other features and advantages of the present invention will become apparent from the following detailed description of preferred embodiments which, taken in conjunction with the accompanying drawings, illustrate by way of example the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1, is a flattened plan view of a section of stent of the present invention in its collapsed state.

FIG. 2 is a flattened plan view of a section of an alternative
5 embodiment stent in its collapsed state.

FIG. 3 is flattened plan view of a section of another alternative embodiment stent in its collapsed state.

FIG. 4 is flattened plan view of a section of another alternative embodiment stent in its collapsed state.

10 FIG. 5 is view of the stent shown in FIG. 4, in its partially expanded state.

FIG. 6 is view of the stent shown in FIG. 5 in a further expanded state.

FIG. 7 is a flattened plan view of a section of yet another alternative
15 embodiment stent of the present invention in its collapsed state.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention is directed to a stent formed from tube stock having a configuration that imparts greater coverage and expansion ratios than heretofore have been possible without compromising strength. Each of the figures illustrates a
20 section of such stents in a flattened plan view for enhanced clarity. Typically, the

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stents of the present invention are formed from tubular members utilizing a chemical etching process or by a laser cutting process. A typical chemical etching process is disclosed in U.S. Patent No. 5,421,955 (Lau et al.), which is commonly assigned and commonly owned by Advanced Cardiovascular Systems, Inc., and which is incorporated herein by reference thereto. Preferably, stents according to the present invention are formed by a laser cutting process as disclosed in U.S. Patent Application Serial No. 08/783,698, which is commonly assigned and commonly owned by Advanced Cardiovascular Systems, Inc., and which is incorporated herein by reference thereto.

FIG. 1 illustrates the general concept of the present invention. Shown is an assembly 12 of serpentine elements 14 wherein apexes 16 of adjacent elements are nested between one another. In its three dimensional form, each serpentine element extends circumferentially about the stent such that for example, end 20 is attached to end 22. The total number of elements assembled in such fashion determine the overall length of the stent. Each of the parallel serpentine elements is joined to the adjacent elements by bridging members 18 that extend from the apexes located along one edge of the serpentine element. Such apexes are alternately joined to the corresponding apexes of the proximally and distally adjoining serpentine elements.

FIG. 2 illustrates an alternative embodiment nested design 24 wherein further improvement in terms of coverage area is realized with the modification of the bridging elements 26. Each bridging element is widened to achieve a commensurate increase in surface area. Sufficient clearance 28, 30 is maintained between the bridging element and the adjoining sections of the serpentine elements so as to preclude contact and interference during expansion.

FIG. 3 illustrates a further alternative embodiment 32 wherein the stresses generated during expansion of the stent near the junction 34 of the bridging element 36 with the concave side 38 of the apex 40 are reduced when compared to the embodiments shown in Figs. 1 and 2. The configurations shown in Figs. 1 and

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2 define acute angles at such junctures along with an increased concentration of mass at such point. During expansion, the bending of the material would therefore be concentrated adjacent the acute corners and greatly diminished at the center of the apex and thereby promote fractures and the potential for failure. By eliminating
5 the acute angles and the concentration of mass at the apex with its formation into a "W" shape, stress is more evenly distributed along the apex during expansion.

FIG. 4 illustrates a further alternative embodiment 42 which incorporates the advantageous features of the embodiment shown in FIG. 3 along with additional features that serve to increase the stent's coverage area as well as its
10 expansion ratio. As is visible in the figure, the transverse section 44 of each serpentine element that links successive apexes 46, 48 is curved at 50 to accommodate the apex of the adjacent serpentine element and to thereby achieve denser packing. The sections are sufficiently curved to come as close as possible to the bridge member at 52 prior to curving around the adjacent apex. Alternating
15 sections are sufficiently curved to substantially close off the apex at 54. The configuration imparts a substantially enhanced coverage area and expansion ratio while nonetheless allowing for the stent to undergo unimpeded expansion. FIG. 5 illustrates such stent configuration partially expanded to show the lack of interference as all elements are caused to move away from one another. FIG. 6
20 illustrates the stent in a substantially more expanded state. The configuration shown in FIG. 6 yields a theoretical expansion ratio of up to 6.7.

FIG. 7 illustrates the most preferred embodiment of the present invention which incorporates many of the features of the embodiments shown in the other Figures, including the nested configuration of parallel serpentine elements,
25 bridging members joining corresponding apexes of adjacent serpentine elements, the stress-relieved "W" patterned apex and the curved linking segments. The wider serpentine elements and bridging members along with the tighter radii yield a stent with an exceptionally high coverage area and expansion ratio along with substantial strength.

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The stents of the present invention are preferably formed utilizing laser cutting techniques well known in the art. The material used in the manufacture of such stents may be substantially worked stainless steel or low ductility materials such as titanium for balloon expandable versions. Alternatively, NiTi may be used
5 for self expanding embodiments.

While a particular form of the invention has been illustrated and described, it will also be apparent to those skilled in the art that various modifications can be made without departing from the spirit and scope of the invention. The present invention is not limited to stents for any particular body
10 lumen. The size of the stent can vary in terms of inner diameter, outer diameter, wall thickness and length. Accordingly, it is not intended that the invention be limited except by the appended claims.

WHAT IS CLAIMED IS :

1. A stent, comprising:
a series of circumferentially disposed serpentine elements, each such elements including a series of apexes extending toward a proximal side and a series
5 of apexes extending toward a distal side, wherein apexes of adjacent serpentine elements are nested within one another and wherein adjacent serpentine elements are linked by bridging members extending between apexes located on the same side of each element.
2. The stent of claim 1, wherein the bridging elements extending from a serpentine element alternately extend between the apexes of the distally and proximally adjoining serpentine elements.
3. The stent of claim 2, wherein the bridging elements extend between apexes extending toward the distal side.
4. The stent of claim 3, wherein each distally extending apex that is linked to a distally extending apex of a proximally adjoining serpentine element is "W" shaped.
5. The stent of claim 2, wherein the bridging elements extend between apexes extending toward the proximal side.

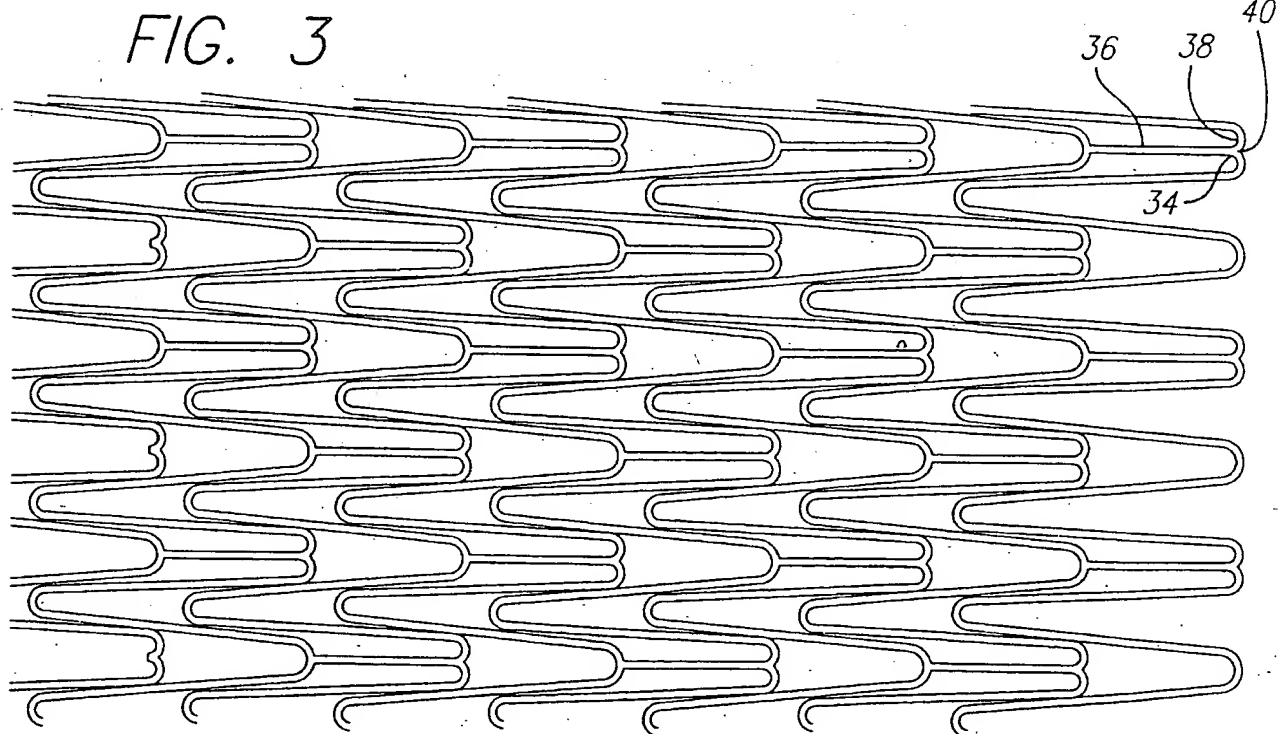
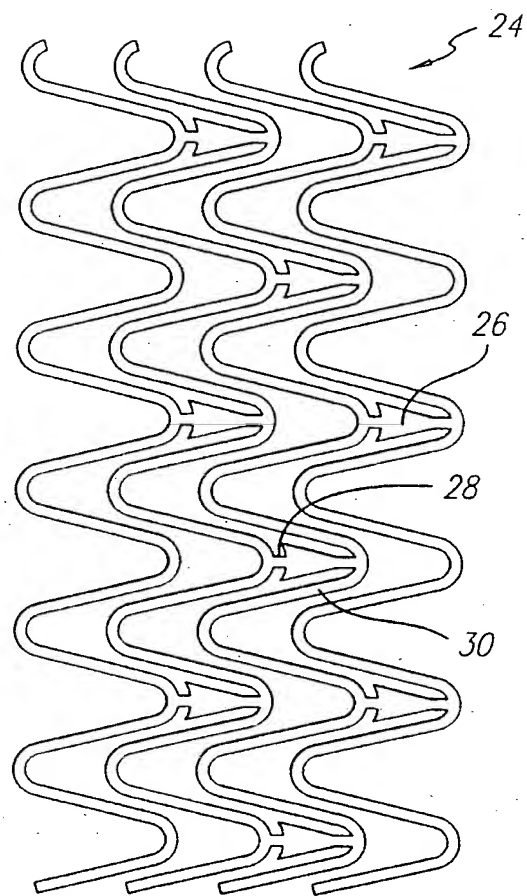
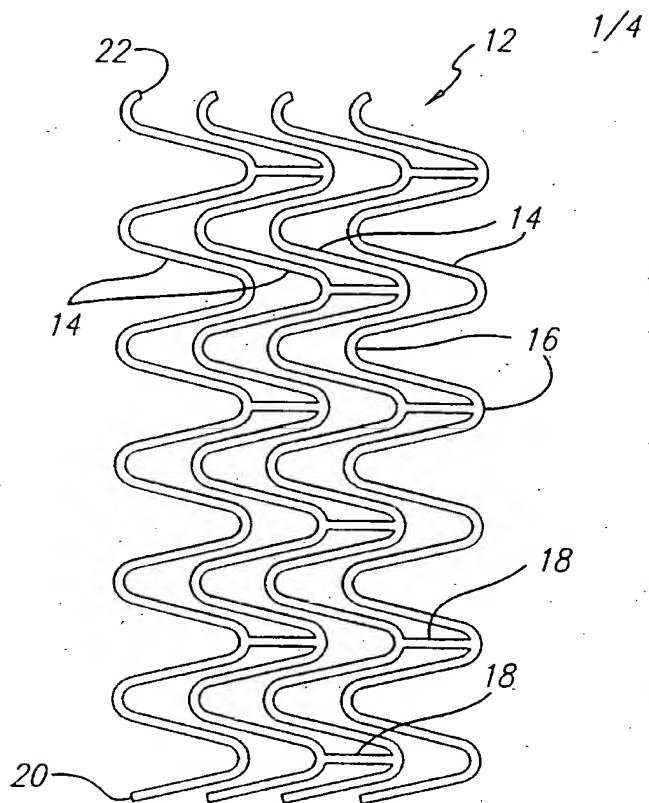
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6. The stent of claim 5, wherein each proximally extending apex that is linked to a proximally extending apex of a distally adjoining serpentine element is "W" shaped.

7. The stent of claim 2, further comprising transverse sections extending between apexes of serpentine elements which are sufficiently curved such that transverse sections extending from the same apex substantially contact one another.

8. The stent of claim 2, further comprising transverse sections extending between apexes of serpentine elements which are sufficiently curved so as to substantially contact bridging elements extending therebetween.

9. The stent of claim 1, wherein the stent is formed from a metal alloy taken from the group of alloys consisting of stainless steel, titanium, tantalum, and nickel-titanium.



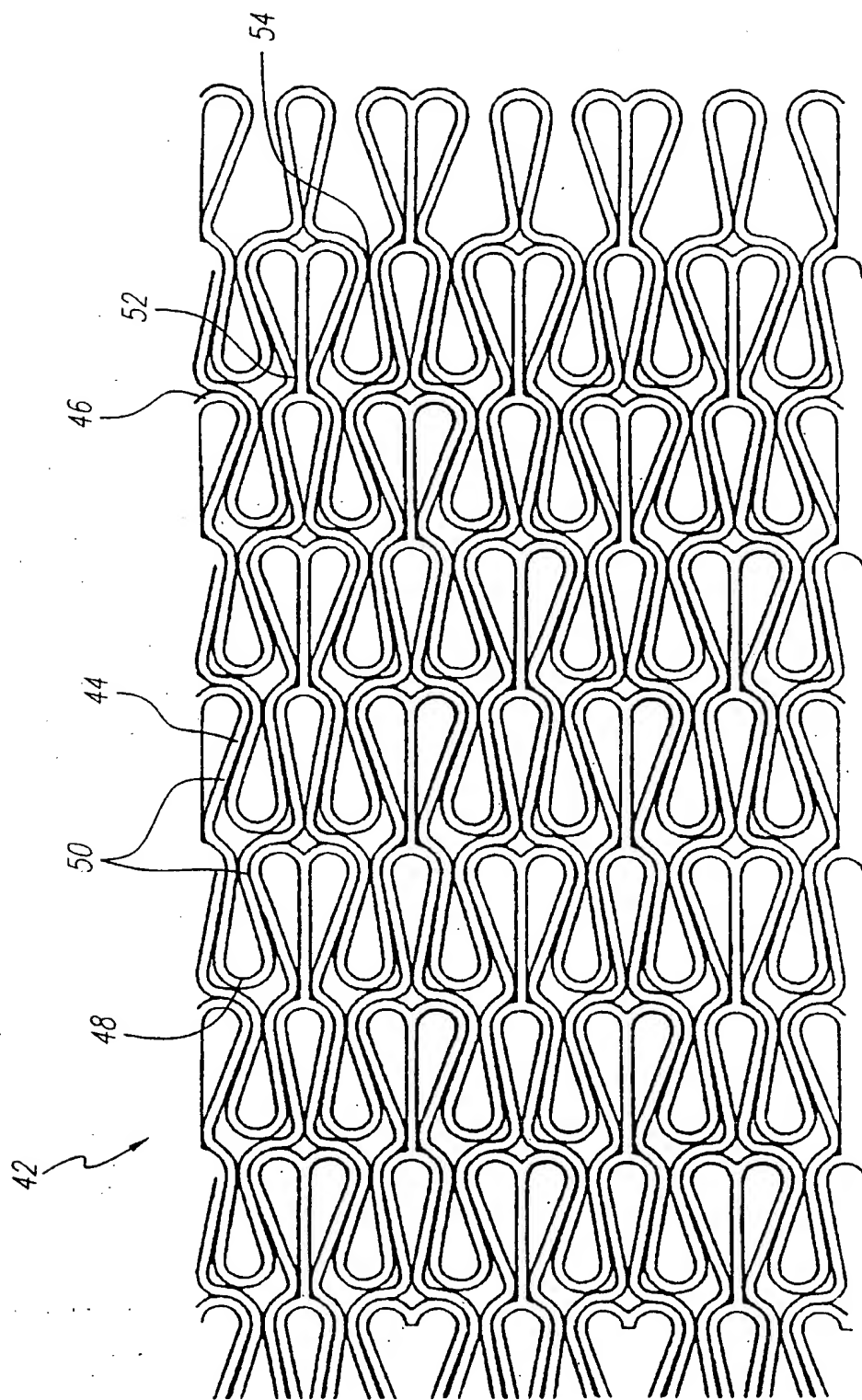
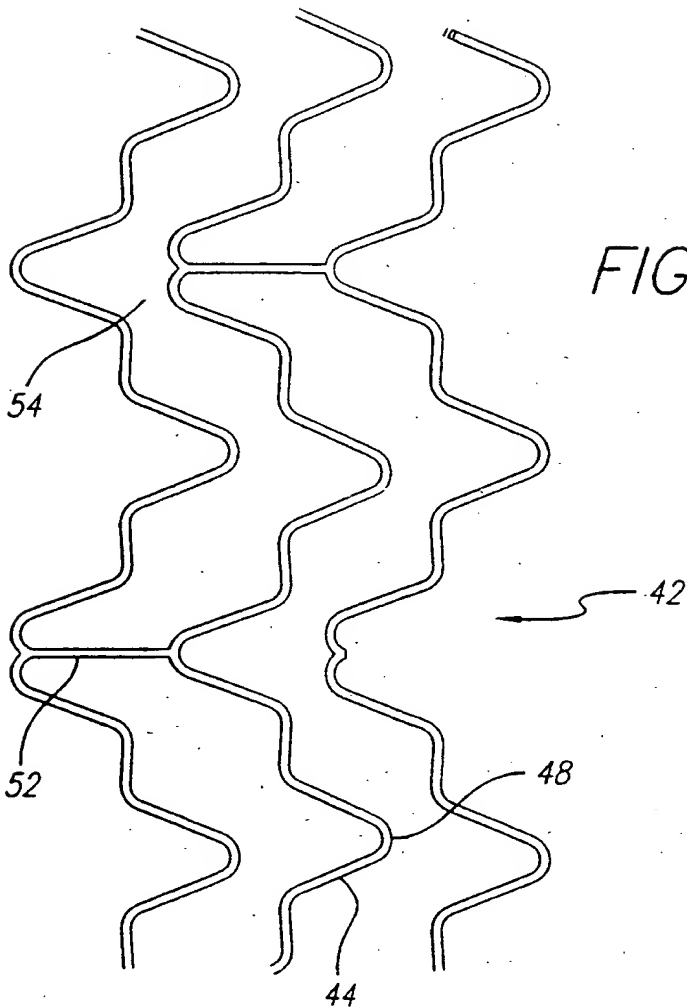
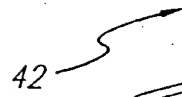
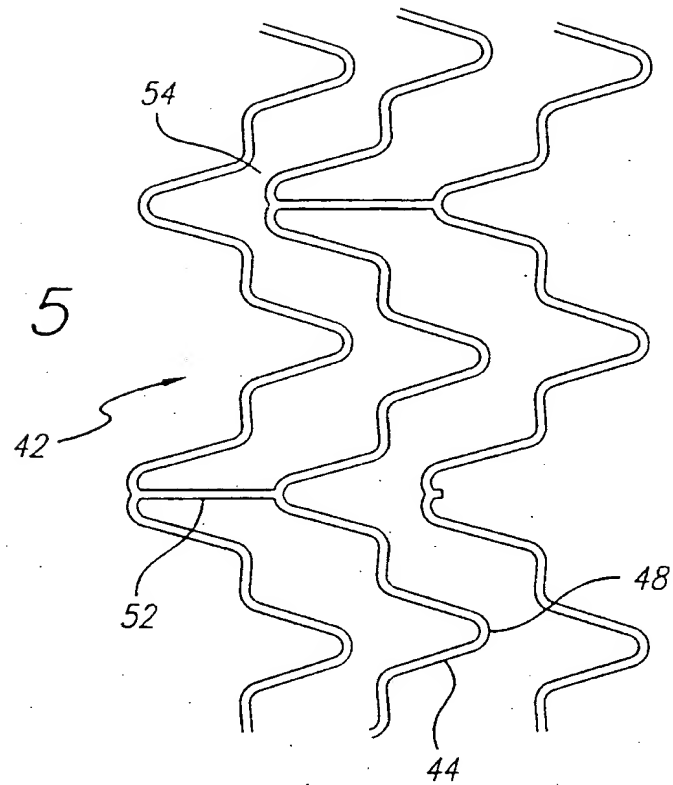
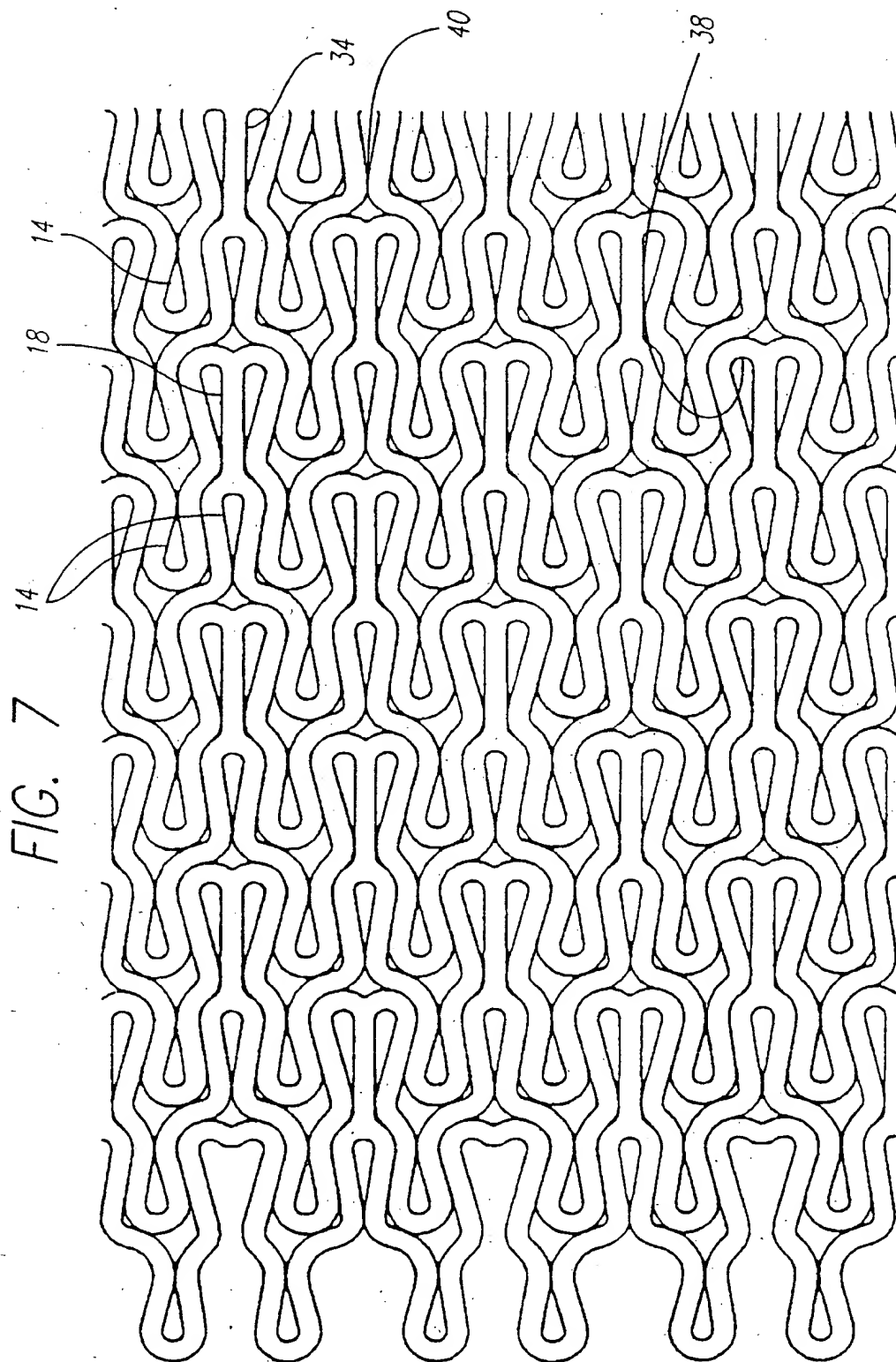


FIG. 4

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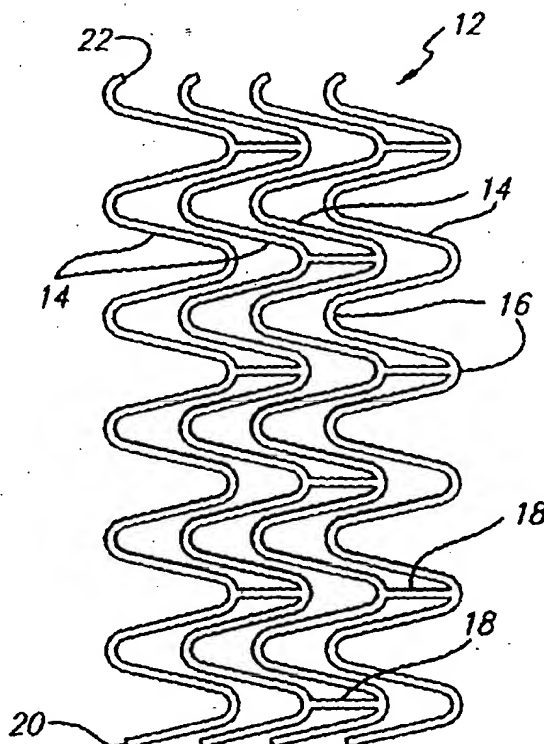


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(54) Title: EXPANDABLE STENT AND METHOD OF USE**(57) Abstract**

A configuration for expandable stents wherein a series of circumferentially disposed serpentine elements are spaced such that apexes defined by adjacent serpentine elements are nested within one another and only apexes extending along the same side of each serpentine element are linked. Such configurations impart enhanced coverage areas, expansion ratios and radial strength to the stent.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/13618

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9709945 A1 (WILLIAM COOK EUROPE A/S), 20 March 1997 (20.03.97), page 12, line 29 - page 13, line 29, figures 1,5, abstract	1-6,9
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X	WO 9726840 A1 (DEKA PRODUCTS LIMITED PARTNERSHIP), 31 July 1997 (31.07.97), page 6, line 25 - page 7, line 14, figures 6-7, abstract	1-6,9
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